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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,676	08/02/2002	Bruno Tocque	50146/003002	9433

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EXAMINER	
CALAMITA, HEATHER	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,676	TOCQUE ET AL.	
	Examiner	Art Unit	
	Heather G. Calamita, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-66* is/are pending in the application.

4a) Of the above claim(s) *58-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-49 and 53-56* is/are rejected.

7)☒ Claim(s) *51,52 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/6/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 40-57, drawn to a method of analysis of a test compound.

Group II, claim(s) 58-60, drawn to a kit.

Group III, claim(s) 61-62, drawn to a nucleic acid library.

Group IV, claim(s) 63, drawn to a process of production of genetic markers.

Group V, claim(s) 64, drawn to a process of preparation of a DNA chip.

Group VI, claim(s) 65, drawn to a method for the identification of SNPs.

Group VII, claim(s) 66, drawn to a method for evaluating a response to a test compound.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13,2, they lack the same or corresponding special technical features for the following reasons: The kit of claims 58-60 are not joined to the methods of at least claims 40, 61 and 63-66. The kit is required to comprise the structural components of a nucleic acid library containing at least one nucleic acid clone specific for Aldolase A. This is not a special technical feature which joins the claimed inventions because Weiner et al. (US2003/0092033 A1) teach a nucleic acid library containing Aldolase (see paragraph 0350). The methods of claims 63-66 are not limited in scope so as to require the products of claims 58-60 and therefore are not joined to claims 58-60 by a special technical feature.

Sequence Election Requirement Applicable to All Groups

3. In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. Furthermore, the sequence searching in multiple expansive databases has put undue burden on the examiner and office resources. For

an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequence (See MPEP 803.04).

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).
>
> It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, **one** independent and distinct nucleotide sequence will be examined in a single application without restriction. In addition to the specifically selected sequence, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

During a telephone conversation with Todd Armstrong on November 23, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 40-57. Affirmation of this election must be made by applicant in replying to this Office action. Claims 58-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-49, 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Fong et al. (Biochimica et Biophysica Acta., Janurary 2001).

Fong et al. teach (claim 40) a method of analysis of the toxic potential of a test compound, said method comprising separately contacting, under conditions allowing hybridization to occur (see abstract first sentence).

a) labeled nucleic acid probes corresponding to RNA molecules from mammalian cells treated with said test compound on the one hand and from untreated mammalian cells on the other hand, with (see p. 251 col. 1 second full paragraph).

b) a library of nucleic acids, wherein said library comprises immobilized on a support, nucleic acid clones specific for splicing forms of genes, said splicing forms being characteristic of apoptosis, the hybridization profile indicating the toxic potential of the test compound (see p. 251 col. 1 second full paragraph). With regard to claim 41, Fong et al. teach the nucleic acid probes correspond to messenger RNAs from treated and untreated cells (see p. 251 col. 1 second full paragraph, p. 252 Figure 1 legend). With regard to clam 42, Fong et al. teach the nucleic acid probes are cDNA or cDNA fragments prepared from RNAs of treated and untreated cells (see p. 251 col. 1 second full paragraph, p. 252 Figure 1 legend). With regard to claim 43, Fong et al. teach the nucleic acid probes are amplification products (see p. 251 col. 1 second full paragraph, p. 252 Figure 1 legend), in order to obtain a labeled cDNA you must go through at least one round of amplification). With regard to claim 44, Fong et al. teach the nucleic acid probes are labeled by radioactive, fluorescent, enzymatic or colorimetric labels (see p. 251 col. 1 second full paragraph). With regard to claim 45, Fong et al. teach the test compound is an individual compound or is present in a mixture with other substances (see p. 250 col. 2 lines 11-15). With regard to claim 46, Fong et al. teach the library comprises nucleic acid clones specific for genes whose level of expression is modified in a situation of apoptosis (see p. 251 col. 1 second full paragraph). With regard to claim 47, Fong et al. teach the library is prepared by hybridizing a

first nucleic acid population from a mammalian cell in a situation of apoptosis and a second nucleic acid population form a cell in a control situation separating from the hybrids formed nucleic acids in an unpaired region (see p. 251 col. 1 second full paragraph, p. 254 first full paragraph). With regard to claim 48, Fong et al. teach apoptosis is produced by induction or enhancement in said mammalian cell of the activation of the anti-oncogene (see p. 254 col. 2 first full paragraph). With regard to claim 49, Fong et al. teach the anti-oncogene is p53 (see abstract). With regard to claim 50, Fong et al. teach the library comprises nucleic acid clines specific for at least part of a gene WAF-1 (see abstract). With regard to claim 53 Fong et al. teach the treated or untreated cells are of human origin (see p. 251 col. 1 first full paragraph). With regard to claim 54 Fong et al. teach the treated or untreated cells are cell lines (see p. 251 col. 1 first full paragraph). With regard to claim 55, Fong et al. teach the treated or untreated cells are primary cultures (see p. 251 col. 1 first full paragraph). With regard to claim 56, Fong et al. teach (i) labeled nucleic acid probes corresponding to mRNA molecules form untreated mammalian cells and a library of immobilized nucleic acids where the library comprises different nucleic acid clones comprising a sequence complementary to at least a portion of a gene that is spliced or whose expression is altered during apoptosis in a mammalian cell (ii) labeled nucleic acid probes corresponding to mRNA molecules from mammalian cells treated with said test compound and said nucleic acid library the hybridization profile indicating the toxic potential of the test compound (see p. 251 col. 1 second full paragraph, p. 252 Figure 1 legend).

Allowable Subject Matter

5. Claims 51, 52 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and removal of the non elected sequences. SEQ ID NO 16 is free of the prior art.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday thru Thursday 7:00 A.M. - 5:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

JEFFREY FREDMAN
PRIMARY EXAMINER
12/9/04